

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

**SANDOZ INC. and ALCON
LABORATORIES, INC.,**

Plaintiffs,

v.

**DUKE UNIVERSITY, ALLERGAN
SALES, LLC., and ALLERGAN, INC.,**

Defendants.

Civil Action No. 1:17-cv-823

DEMAND FOR JURY TRIAL

COMPLAINT FOR DECLARATORY JUDGMENT

Sandoz Inc. (“Sandoz”) and Alcon Laboratories, Inc. (“Alcon” and collectively with Sandoz, “Plaintiffs”)¹ file this complaint for declaratory judgment against Allergan Sales, LLC (“Allergan Sales”), Allergan, Inc. (collectively with Allergan Sales, “Allergan”) and Duke University (“Duke” and collectively with Allergan, “Defendants”) and allege as follows:

NATURE OF THE ACTION

1. This is a declaratory judgment action arising under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.* and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* Sandoz is currently selling an ophthalmic solution of bimatoprost (0.03%), which is a generic version of LATISSE® and is indicated to treat hypotrichosis of the eyelashes by increasing their growth including length, thickness and darkness. Allergan, Inc. and/or Duke have previously asserted patents with method of treatment claims related to this product in three prior litigations. As detailed below, each of the prior litigations were filed before this Court. Allergan, Inc. and/or

¹ Plaintiffs do not believe Alcon is a necessary party to this action. It is named here because Defendants recently sued Sandoz and Alcon in a case related to the same subject matter in the Eastern District of Texas. Plaintiffs will move pursuant to 28 U.S.C. § 1404(a) to transfer that case to this District due to judicial efficiency.

Duke lost each time. In the first litigation, the asserted patent claims were adjudged as invalid due to obviousness. *Allergan, Inc. v. Apotex, Inc.*, 754 F.3d 952, 964-66 (Fed. Cir. 2014). Despite this, Allergan, Inc. asserted additional patent claims from multiple related patents directed to substantially the same invention in not one, but two more litigations. It is not surprising that this Court and the Federal Circuit found that Allergan, Inc. was collaterally estopped from asserting those patent claims or contesting their validity in those litigations. If that were not enough, Duke and Allergan Sales, *now for the fourth time*, have asserted substantially similar patent claims to those of the prior litigations. This time, the only meaningful differences are that a new patent number is involved (United States Patent No. 9,579,270 (“the ’270 patent”)) and that Defendants have forum-shopped to the Eastern District of Texas. The foregoing prompted the present declaratory judgment action. This Court should invalidate the ’270 patent and disallow Defendants’ anti-competitive behavior for at least the reasons herein.

2. Plaintiffs seek a declaration of invalidity, unenforceability, and non-infringement of the ’270 patent.

3. Plaintiffs further seek a declaration that Defendants are precluded from asserting claims 22 and 30 of the ’270 patent against Plaintiffs due to collateral.

4. Plaintiffs further seek a declaratory judgment that Defendants’ assertion of the ’270 patent against Plaintiffs (*see Duke Univ. v. Sandoz Inc.*, No. 2:17-cv-528 (July 7, 2017 E.D. Tex.)) constitutes patent misuse.

5. Sandoz further seek a declaratory judgment that Defendants’ assertion of the ’270 patent against Plaintiffs (*see Duke Univ. v. Sandoz Inc.*, No. 2:17-cv-528 (July 7, 2017 E.D. Tex.)) constitutes sham litigation and a violation of Section 2 of the Sherman Act, 15, U.S.C. § 2

as well as a declaration that Defendants are precluded from asserting claims 22 and 30 of the '270 patent against Plaintiffs due to equitable estoppel.

6. Lastly, Plaintiffs seek a declaratory judgement for treble damages.

THE PARTIES

7. Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, having a place of business at 100 College Road West, Princeton, New Jersey 08540.

8. Alcon Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 6201 South Freeway, Fort Worth, Texas 76134-2099.

9. On information and belief, Duke University is a non-profit corporation organized and existing under the laws of the state of North Carolina, having a place of business at 310 Blackwell Street, Durham, North Carolina 27701-3661.

10. On information and belief, Allergan Sales, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 2525 DuPont Drive, Irvine, California 92612.

11. On information and belief, Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2525 DuPont Drive, Irvine, California 92612.

12. On information and belief, Allergan, Inc. is the corporate parent of Allergan Sales, LLC.

13. Upon information and belief, Allergan, Inc. and Allergan Sales are both controlled and entirely owned by the same corporate entity, Allergan plc.

JURISDICTION AND VENUE

14. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

15. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202 and 35 U.S.C. § 1, *et seq.*

16. An actual, substantial and continuing justiciable controversy exists between Plaintiffs and Defendants, with respect to which Plaintiffs require a declaration of their rights by this Court. Specifically, the controversy relates to the invalidity, unenforceability, and non-infringement of the '270 patent, and to the right of Defendants to maintain a suit for alleged infringement of the '270 patent against Plaintiffs.

17. On information and belief, Duke maintains offices and campuses in this district.

18. On information and belief, Duke regularly transacts business in North Carolina and specifically in this district.

19. On information and belief, Duke owns property in this district.

20. On information and belief, at least one inventor of the alleged invention described and claimed in the '270 patent resides in this district or within 100 miles of this district.

21. On information and belief, Allergan regularly transacts business in the Middle District of North Carolina and has purposefully advertised, sold, and distributed its products to customers in North Carolina and in this judicial district.

22. On information and belief, Allergan has also advertised, sold and distributed its products into the stream of commerce in the United States with the reasonable belief and expectation that such products would periodically flow into North Carolina and into this judicial district.

23. On information and belief, Allergan has sales employees in this district.

24. Duke has subjected itself to this Court's jurisdiction by filing suit as a Plaintiff in related litigations involving the same product at issue as in this litigation (*e.g.*, Civil Action Nos. 1:11-cv-298-CCE; 1:14-cv-1034-CCE).

25. Allergan has subjected itself to this Court's jurisdiction when Allergan, Inc. filed suit as a Plaintiff in related litigations involving the same product as at issue in this litigation (*e.g.*, Civil Action Nos. 1:11-cv-298-CCE, 1:12-cv-247-CCE, and 1:14-cv-1034-CCE).

26. This Court has personal jurisdiction over Duke.

27. This Court has personal jurisdiction over Allergan.

28. Duke has represented that venue is proper in this judicial district in related litigations involving the same product at issue as in this litigation (*e.g.*, Civil Action Nos. 1:11-cv-298-CCE; 1:14-cv-1034-CCE).

29. Allergan, Inc. has represented that venue is proper in this judicial district in related litigations involving the same product at issue as in this litigation (*e.g.*, Civil Action Nos. 1:11-cv-298-CCE, 1:12-cv-247-CCE, and 1:14-cv-1034-CCE).

30. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c).

BACKGROUND FACTS

A. The '270 Patent

31. The '270 patent is entitled "Compositions and Methods for Treating Hair Loss Using Non-Naturally Occurring Prostaglandins" and bears an issuance date of February 28, 2017. A copy of the '270 patent is attached hereto as Exhibit 1.

32. On information and belief, Duke is the assignee of the '270 patent.

33. On information and belief, Allergan, Inc. and Allergan Sales are the exclusive licensees of the '270 patent.

B. Bimatoprost Ophthalmic Solution Products

34. On information and belief, Allergan, Inc. is the holder of approved New Drug Application (“NDA”) No. 22-369 for bimatoprost ophthalmic solution, 0.03%, sold by Allergan Sales, LLC in the United States under the LATISSE® registered trademark.

35. On information and belief, Allergan, Inc. is the corporate parent of Allergan Sales, LLC.

36. On information and belief, FDA approved LATISSE® in 2008.

37. On information and belief, LATISSE® is indicated to treat hypotrichosis of the eyelashes by increasing their growth, including length, thickness, and darkness.

38. On information and belief, LATISSE® has resulted in net sales for Allergan of over \$70 million annually since its launch in 2009.

39. Sandoz is the holder of Abbreviated New Drug Application (“ANDA”) No. 20-2719 for bimatoprost ophthalmic solution, 0.03%.

40. FDA approved ANDA No. 20-2719 for bimatoprost ophthalmic solution, 0.03%, in or around April 2016.

41. Sandoz launched bimatoprost ophthalmic solution, 0.03% as described in ANDA No. 20-2719 (hereinafter, Sandoz’s “bimatoprost ophthalmic solution, 0.03% product”), in or around December 2016.

42. Sandoz’s bimatoprost ophthalmic solution, 0.03% product is indicated to treat hypotrichosis of the eyelashes by increasing their growth, including length, thickness, and darkness.

43. According to Allergan, Inc.’s website and marketing materials, LATISSE®, Allergan’s 0.03% bimatoprost topical solution product, is the first and only FDA-approved treatment for hypotrichosis of the eyelashes.

44. Sandoz received FDA approval to market and sell a bimatoprost ophthalmic solution, 0.03% product on April 19, 2016.

45. Sandoz's bimatoprost ophthalmic solution, 0.03% product has been approved by FDA to treat hypotrichosis of the eyelashes.

46. Sandoz launched bimatoprost ophthalmic solution, 0.03%, in or around December 2016.

47. On information and belief, Sandoz and Allergan Sales are currently the only competitors marketing FDA approved products to treat hypotrichosis of the eyelashes.

Defendants' Anticompetitive Conduct and Scheme

C. Defendants' Serial And Repetitive Litigations Against Sandoz Relating To Sandoz's 0.03% Bimatoprost Ophthalmic Solution Product

48. Allergan, Inc. and/or Duke previously litigated three cases against Sandoz relating to patent infringement based on Sandoz's marketing and sale of its bimatoprost ophthalmic solution, 0.03% product.

49. Allergan Sales and Duke recently filed a fourth case in the Eastern District of Texas involving substantially similar patent claims and the same accused product previously litigated in the Middle District of North Carolina. *See infra*.

1. *Latisse I*

50. On April 15, 2011, Allergan, Inc. and Duke filed suit against Sandoz alleging, among other things, that Sandoz's proposed bimatoprost ophthalmic solution, 0.03% product infringed U.S. Patent Nos. 7,388,029 (the "'029 patent") and 7,351,404 (the "'404 patent"). *Allergan, Inc. v. Sandoz, Inc.*, No. 1:11-cv-298-CCE at Dkt. No. 1 (Complaint) (litigation hereinafter referred to as "*Latisse I*").

51. Allergan, Inc. and Duke brought suit in the Middle District of North Carolina in *Latisse I*.

52. Allergan, Inc. and Duke thus selected the Middle District of North Carolina as its preferred forum for litigating *Latisse I*.

53. The Federal Circuit in *Latisse I* held that the asserted claims of the '029 and '404 patents were invalid as obvious. *Allergan, Inc. v. Apotex, Inc.*, 754 F.3d 952 (Fed. Cir. 2014).

54. After the Federal Circuit issued its mandate, this Court entered judgment of invalidity and non-infringement with respect to the asserted claims of the '029 and '404 patents. (11-cv-298 Doc. 125; 10-cv-681 Doc. 250).

2. *Latisse II*

55. On March 13, 2012 and January 8, 2013, Allergan, Inc. sued Sandoz for purported patent infringement relating to the sale of Sandoz's bimatoprost ophthalmic solution, 0.03% product, this time alleging that the accused bimatoprost product infringed U.S. Patent Nos. 8,038,988 (the "'988 patent"), 8,101,161 (the "'161 patent"), and 8,263,054 (the "'054 patent"). *Allergan, Inc. v. Apotex Inc. et al.*, No. 1:12-cv-247 at Dkt. No. 1, 1:13-cv-16, Dkt. No. 1 (Complaints) (litigation hereinafter referred to as "*Latisse II*").

56. Allergan, Inc. brought suit in the Middle District of North Carolina in *Latisse II*.

57. Allergan, Inc. thus selected the Middle District of North Carolina as its preferred forum for litigating *Latisse II*.

58. This Court held that the '988, '161, and '054 patents asserted in *Latisse II* are related to, and recite substantially the same subject matter as, the '404 patent, which had been invalidated in *Latisse I*. *Allergan, Inc. v. Apotex Inc. et al.*, No. 1:12-cv-247 at Dkt. No. 114, p. 2; 1:13-cv-16 at Dkt. No. 77 (Final Judgment), p. 2.

59. Accordingly, this Court entered a Final Judgment holding Allergan, Inc. collaterally estopped from asserting or contesting the invalidity of the '988, '161, and '054 patents in light of the Federal Circuit's finding of invalidity of the '404 patent. No. 1:12-cv-247 at Dkt. No. 114, p. 3; 1:13-cv-16 at Dkt. No. 77 at p. 3.

60. This Court subsequently dismissed Allergan, Inc.'s claims of infringement against Sandoz. No. 1:12-cv-247 at Dkt. No. 115; 1:13-cv-16 at Dkt. No. 78 (Order and Judgment).

61. Allergan, Inc. did not appeal this Court's order of dismissal or its underlying holding that Allergan be collaterally estopped from asserting or contesting the invalidity of the patent claims asserted in *Latisse II*.

3. *Latisse III*

62. On December 10, 2014, Allergan, Inc. and Duke sued Sandoz in the Middle District of North Carolina for purported patent infringement relating to the sale of Sandoz's bimatoprost ophthalmic solution, 0.03% product, this time alleging that the accused bimatoprost product infringed U.S. Patent Nos. 8,906,962 (the "'962 patent") and 8,926,953 (the "'953 patent"). *Allergan, Inc. v. Sandoz, Inc. et al.*, No. 1:14-cv-1034 at Dkt. No. 15 (First Amended Complaint) (litigation hereinafter referred to as "*Latisse III*").

63. Allergan, Inc. and Duke brought suit in the Middle District of North Carolina in *Latisse III*.

64. Allergan, Inc. and Duke thus selected the Middle District of North Carolina as its preferred forum for litigating *Latisse III*.

65. During the pendency of *Latisse III*, Allergan, Inc. and Duke dropped its allegations as to infringement of the '962 patent and chose to focus on certain claims of the '953 patent. *Allergan, Inc. v. Sandoz, Inc.*, No. 1:14-cv-1034 at Dkt. 47.

66. Upon information and belief, Allergan, Inc. and Duke dropped the allegations as to infringement of the '962 patent as a result of the Federal Circuit's ruling in *Latisse I*, which held asserted claims of the related '029 patent invalid.

67. As to the remaining '953 patent, on August 31, 2015, this Court entered an Order and Judgment in favor of Sandoz finding Allergan, Inc. collaterally estopped from asserting the '953 patent against Sandoz or contesting its invalidity. *Allergan, Inc. v. Sandoz, Inc.*, No. 1:14-cv-1034 at Dkt. No. 71 (Order and Judgment), p. 2.

68. In explaining its holding, this Court noted that the '953 patent "claims priority to, and [recites] substantially the same subject matter as, invalid '404 patent claim 14 [which had been invalidated in *Latisse I*] and the relevant claims of the '054, '161, and '988 patents [which had been invalidated in *Latisse II*]." *Id.*

69. This Court dismissed Allergan, Inc.'s claims of infringement against Sandoz with prejudice. *Id.*

70. The Federal Circuit in *Latisse III* affirmed the district court's holding that the asserted Claims 8, 23, and 26 of the '953 patent were invalid on the basis of collateral estoppel. *Allergan, Inc. v. Sandoz, Inc.*, 681 Fed. Appx. 955, 960-963 (Fed. Cir. Mar. 17, 2017) (stating that "We agree with the District Court that the Asserted Claims are substantially similar to the invalidated claims of the '404, '054, '161, and '988 patents, and that any differences between the claims do not materially alter the question of invalidity.").

4. Latisse IV

71. On July 7, 2017, Allergan Sales and Duke filed a fourth action against Sandoz and, for the first time, Alcon, for purported patent infringement relating to the sale of Sandoz's bimatoprost ophthalmic solution, 0.03% product, this time alleging that the accused bimatoprost

product infringed Claims 22 and 30 of the '270 patent. *Duke Univ. v. Sandoz Inc.*, No. 2:17-cv-528-RG (July 7, 2017 E.D. Tex.) (litigation hereinafter referred to as "*Latisse IV*").

72. Allergan Sales and Duke filed *Latisse IV* in the Eastern District of Texas despite filing three prior suits involving the same Sandoz product in the Middle District of North Carolina.

73. *Latisse IV* is currently pending before Judge Gilstrap.

74. A motion to transfer *Latisse IV* to this district will be filed in the Eastern District of Texas.

75. The '270 patent asserted in *Latisse IV* shares a common specification with, and claims priority to, the '029 patent, for which the asserted claims were held obvious by the Federal Circuit in *Latisse I. Allergan, Inc. v. Apotex, Inc.*, 754 F.3d 952 (Fed. Cir. 2014); *Allergan, Inc. v. Sandoz, Inc.*, No. 1:11-cv-298-CCE at Dkt. No. 125 (Final Judgment), p. 2.

76. Both the '270 and '029 patents claim priority to the same March 31, 2000 provisional application.

77. Allergan Sales and Duke asserted Claims 22 and 30 of the '270 patent against Plaintiffs in *Latisse IV*.

78. Claims 22 and 30 of the '270 patent are substantially similar to the claims invalidated as obvious in *Latisse I*.

79. Claims 22 and 30 of the '270 patent are substantially similar to the claims for which Allergan, Inc. and Duke were collaterally estopped from contesting invalidity in *Latisse II*.

80. Claims 22 and 30 of the '270 patent are substantially similar to the claims for which Allergan, Inc. and Duke were collaterally estopped from contesting invalidity in *Latisse III*.

C. Allergan, Inc.'s Orange Book Listing of Other Bimatoprost Products

81. Upon information and belief, Allergan, Inc. is the holder of New Drug Application (“NDA”) No. 021275 for bimatoprost ophthalmic solution, 0.03%.

82. Upon information and belief, on or around March 16, 2001, FDA approved Allergan, Inc.'s NDA No. 021275 for bimatoprost ophthalmic solution, 0.03%, for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.

83. Upon information and belief, Allergan, Inc. marketed and sold bimatoprost ophthalmic solution, 0.03% under the tradename Lumigan®.

84. In conjunction with NDA No. 021275, Allergan, Inc. listed with FDA patents that allegedly covered the approved 0.03% formulation of Lumigan®. The FDA published those patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.”

85. Upon information and belief, the bimatoprost active ingredient in Lumigan® 0.03% is the same bimatoprost active ingredient in LATISSE®.

86. Upon information and belief, Lumigan® 0.03% has the same formulation as the formulation for LATISSE®.

87. Upon information and belief, Allergan, Inc. does not currently sell Lumigan® 0.03% in the U.S.

88. Upon information and belief, all patents allegedly covering Lumigan® 0.03% have expired in the U.S.

89. Upon information and belief, Allergan, Inc. is also the holder of NDA No. 022184 for bimatoprost ophthalmic solution, 0.01%.

90. Upon information and belief, on or around August 31, 2010, FDA approved Allergan, Inc.'s NDA No. 022184 for bimatoprost ophthalmic solution, 0.01% for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.

91. Upon information and belief, Allergan, Inc. currently sells bimatoprost ophthalmic solution, 0.01% in the U.S. under the tradename Lumigan®.

92. Upon information and belief, Lumigan® 0.01% is approved for the same indication as Lumigan® 0.03%.

93. In conjunction with NDA No. 022184, Allergan listed with FDA U.S. Patent Nos. 7,851,504, 8,278,353, 8,299,118, 8,309,605, 8,338,479, 8,524,777, 8,586,630, 8,772,338, 8,933,120, 8,933,127, 9,155,716, and 9,241,918 (collectively "Listed Patents") as allegedly covering the approved 0.01% formulation of Lumigan®.

94. FDA published the Listed Patents in the Orange Book.

95. None of the Listed Patents have expired.

D. The Relevant Market

96. The relevant product market is the market for FDA-approved treatments for hypotrichosis of the eyelashes.

97. Because FDA approval is required to sell prescription medications within the U.S., and other countries require that companies obtain local regulatory approval to market prescription medications in those countries, the relevant geographic market is the United States and its territories.

E. Allergan's Market or Monopoly Power in the Relevant Market

98. There are currently no other products in the relevant market other than Allergan's Latisse® and Sandoz's bimatoprost ophthalmic solution, 0.03% products.

99. Allergan had a 100% market share in the market for FDA-approved treatment for hypotrichosis of the eyelashes until December 5, 2016.

100. Upon information and belief, LATISSE® has resulted in net sales of over \$70 million annually.

101. Upon information and belief, Sandoz net sales for 2017 are projected to be approximately \$10-\$15 million from its 0.03% bimatoprost ophthalmic solution, 0.03% product.

102. Upon information and belief, after December 5, 2016, Allergan has had a market share of at least 70% for FDA-approved treatment for hypotrichosis of the eyelashes.

103. Upon information and belief, Allergan could and did impose significant, non-transitory price increases without losing sufficient sales to render 0.03% bimatoprost ophthalmic solution unprofitable.

104. Allergan's non-transitory price increases establish that there is a relevant product market for FDA-approved treatment to grow eyelashes, which is comprised of 0.03% bimatoprost ophthalmic solution.

105. Barriers to entry into the relevant market are high. A new entrant would require substantial capital, technical capability, FDA approval, and a sophisticated distribution and marketing capability to successfully enter the relevant market.

106. Upon information and belief, the average cost of a bringing a new drug to market costs \$1.3 to \$1.4 billion, on average. It can take up to 10 years for a drug to be approved for prescription.

107. Upon information and belief, bringing a new generic pharmaceutical product to market requires tens of millions of dollars and several years to obtain regulatory approval.

108. Upon information and belief, the average time for a decision from the FDA regarding approval of an Abbreviated New Drug Application is about 17 months.

109. Upon information and belief, Sandoz and Allergan Sales are currently the only competitors marketing FDA approved products to treat hypotrichosis of the eyelashes.

110. Allergan possesses market or monopoly power in the relevant market.

F. Continuing Violations

111. Allergan Sales, Allergan, Inc. and Duke have engaged in a continuing course of unlawful conduct, including conduct that occurred during the applicable limitations periods, that has caused continuing harm to Sandoz during the applicable limitations periods. Accordingly, Sandoz is entitled to recover damages for the harm it suffered during the applicable limitations periods.

112. As a result of Allergan Sales, Allergan, Inc. and Duke's fraudulent concealment of their anticompetitive scheme, the running of all applicable statutes of limitations has been tolled with respect to any claims that Sandoz may have arising from Allergan Sales, Allergan, Inc. and Duke's unlawful scheme.

There is an Immediate and Real Controversy Between Plaintiffs and Defendants Regarding the '270 Patent

113. With respect to the litigation currently pending in the Eastern District of Texas, Duke and Allergan Sales have alleged that the making, selling, and offering to sell a bimatoprost ophthalmic solution, 0.03% product by Plaintiffs induces and contributorily infringes Claims 22 and 30 of the '270 patent. *Duke Univ. et al. v. Sandoz Inc. et al.*, No. 2:17-cv-528-RG (July 7, 2017 E.D. Tex.) at Dkt. 1 (Complaint).

114. Sandoz and Alcon have not infringed, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily)

any valid and enforceable claim of the '270 patent, including Claims 22 and 30 of the '270 patent.

115. As a result of Duke and Allergan Sales's allegations of infringement of Claims 22 and 30 of the '270 patent against Sandoz and Alcon, there is an actual and justiciable controversy between the parties concerning infringement and validity of that patent arising under the Patent Act (title 35 U.S.C. §§ 1 *et seq.*).

116. Sandoz and Alcon are entitled to have Duke and Allergan's infringement allegations resolved by virtue of a declaratory judgment of non-infringement, unenforceability and/or invalidity in order to clear the uncertainty created by Defendants' assertion of infringement and attempts to seek injunctive relief against Plaintiffs in the Eastern District of Texas.

COUNT I

Declaration of Preclusion Based on Collateral Estoppel By Sandoz and Alcon Against Duke and Allergan

117. Plaintiffs repeat and reallege the allegations in paragraphs 1-116 as though fully set forth herein.

118. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

119. There is a real, immediate, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Defendants are precluded from asserting Claims 22 and 30 of the '270 patent against Plaintiffs.

120. This controversy is amenable to specific relief through a decree of a conclusive character.

121. Defendants are precluded based on collateral estoppel from asserting infringement of Claims 22 and 30 of the '270 patent against Plaintiffs.

122. Asserted claims of the '029, '404, '054, '988, '161 and '953 patents generally relate to methods of enhancing hair growth. *Allergan, Inc. v. Sandoz, Inc.*, 681 Fed. Appx. 955, 960-61 (Fed. Cir. Mar. 17, 2017); *Allergan, Inc. v. Apotex, Inc.*, 754 F.3d 952, 964-66 (Fed. Cir. 2014).

123. The asserted claims of the '029 and '404 patents were found to be invalid as obvious by the Federal Circuit in *Latisse I. Allergan, Inc. v. Apotex, Inc.*, 754 F.3d 952, 964-66 (Fed. Cir. 2014).

124. Despite the asserted claims of the '029 and '404 patents being found invalid as obvious, Defendants sued Sandoz and Alcon for infringement of the '270 patent.

125. In *Latisse II*, Allergan, Inc. was collaterally estopped from asserting or contesting the invalidity of the '988, '161, and '054 patents. *Allergan, Inc. v. Apotex Inc.*, No. 1:12-cv-247 at Dkt. No. 114; 1:13-cv-16 at Dkt. No. 77 (Final Judgment), p. 3.

126. Despite being collaterally estopped from asserting or contesting the invalidity of the '988, '161, and '054 patents, Defendants sued Sandoz and Alcon for infringement of the '270 patent.

127. In *Latisse III*, Allergan, Inc. was collaterally estopped from asserting or contesting the invalidity of the asserted claims of the '953 patent. *Allergan, Inc. v. Sandoz, Inc.*, 681 Fed.Appx. 955, 964 (Fed. Cir. 2017); *Allergan, Inc. v. Sandoz, Inc.*, No. 1:14-cv-1034 at Dkt. No. 102 (Final Judgment).

128. Despite being collaterally estopped from asserting or contesting the invalidity of the asserted claims of the '953 patent, Defendants sued Sandoz and Alcon for infringement of the '270 patent.

129. Claims 22 and 30 of the '270 patent are substantially similar to at least Claims 1, 8, 14, 18, and 20 of the '029 patent and Claim 14 of the '404 patent, which were previously invalidated as obvious in *Latisse I*.

130. The '029 and '270 patents are related and share the same parent application.

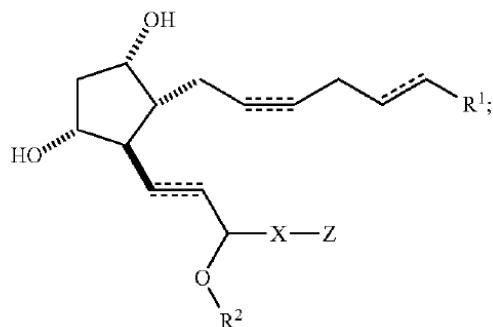
131. The '404, '054, '988, '161 and '953 patents are related and share the same parent application.

132. Claims 22 and 30 of the '270 patent are substantially similar to the claims of the '988, '161, and '054 patents that were previously invalidated on the basis of on collateral estoppel in *Latisse II*.

133. Claims 22 and 30 of the '270 patent are substantially similar to Claims 8, 20, and 23 of the '953 patent, which were previously invalidated on the basis of on collateral estoppel in *Latisse III*.

134. For example, Claim 17 of the '270 patent, from which asserted Claims 22 and 30 depend, recites a method of:

[A]pplying to mammalian skin a safe and effective amount of a composition comprising:
A) an active ingredient selected from the group consisting of a ***prostaglandin F analog*** of the following structure:

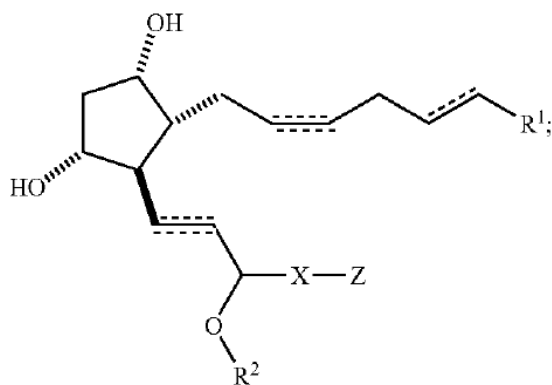


135. For example, invalid claim 1 of the '029 patent recites a method of:

[A]dministering to a mammal a composition comprising:

A) an active ingredient selected from the group consisting of a **prostaglandin F analog** having a structure selected from the group consisting of:

...



136. For example, invalid Claim 1 of the '404 patent describes a “**method of stimulating hair growth** in a mammalian species comprising the **application to mammalian skin.**” Similarly, Claims 22 and 30 of the '270 patent describe a “**method of growing hair** wherein the method comprises topically **applying to mammalian skin**... a composition.”

137. For example, invalid Claim 8 of the '953 patent describes a “**method of enhancing the growth** of ... **hair**, wherein the method comprises **topical application.**” Similarly, Claims 22 and 30 of the '270 patent describe a “**method of growing hair** wherein the method comprises **topically applying** ... a composition.”

138. For example, invalid Claim 1 of the '054 patent describes a “*method of increasing eyelash growth*.” Similarly, Claims 22 and 30 of the '270 patent describe a “*method of growing hair*.”

139. For example, invalid Claim 1 of the '988 patent recites: “[a] *method of increasing* one or more of: *length*, thickness, number, density, luster, sheen, brilliance, gloss, glow, shine and patina of eyelash *hair in a human*.” Similarly, Claims 22 and 30 of the '270 patent describe a “*method of growing hair*.”

140. For example, invalid Claim 21 of the '161 patent recites: “[a] method for stimulating hair follicles to *increase hair growth*.” Similarly, Claims 22 and 30 of the '270 patent describe a “*method of growing hair*.”

141. Claims 22 and 30 of the '270 patent as well as invalid claims from the '029, '404, '054, '988, '161 and '953 patents: 1) apply the same composition; 2) topically; 3) to a mammal; 4) to stimulate hair growth.

142. Thus, there are no differences between asserted Claims 22 and 30 of the '270 patent and claims invalidated by this Court in *Latisse I*, *Latisse II*, and *Latisse III* that would materially alter the conclusion that Claims 22 and 30 of the '270 patent are invalid.

143. In *Latisse IV*, Defendants have purported that Claims 22 and 30 of the '270 patent are narrower in scope than claims invalidated in the prior *Latisse* litigations. Any purported change in claim scope however does nothing to change the identity of issues with respect to invalidity of Claims 22 and 30 of the '270 patent and this Court's invalidity finding in the prior *Latisse* litigations.

144. Claims 22 and 30 of the '270 patent are *prima facie* obvious over the same art that formed the basis of invalidity of asserted claims of the '029 patent in *Latisse I. Allergan, Inc. v. Apotex, Inc.*, 754 F.3d 952, 964-66 (Fed. Cir. 2014).

145. The issuance of the '270 patent in no way changes what the prior art, such as PCT/US98/02289 ("Johnstone") and U.S. Patent No. 5,688,819 (the "'819 patent") teaches or discloses as of the relevant priority date.

146. Those same teachings, *inter alia*, would render the asserted claims of the '270 patent obvious.

147. The Federal Circuit's determinations regarding secondary considerations of non-obviousness from *Latisse I* are equally applicable to the issue of secondary considerations of non-obviousness relevant to Claims 22 and 30 of the '270 patent.

148. In *Latisse I*, the Federal Circuit held that purported unexpected properties were not novel. *Allergan, Inc.*, 754 F.3d at 964-66.

149. Purported unexpected properties are likewise not novel with respect to Claims 22 and 30 of the '270 patent.

150. Claims 22 and 30 of the '270 patent encompass many different compositions.

151. Any allegations of commercial success would rest only on a *single* compound, bimatoprost, such that any alleged commercial success is not commensurate with the full scope of claims 22 and 30 of the '270 patent.

152. Accordingly, the issue of invalidity of Claims 22 and 30 of the '270 patent is identical to the issue of invalidity decided in *Latisse I*.

153. Moreover, Sandoz, Duke and Allergan, Inc. completely litigated the issue of obviousness of the asserted claims of the '029 and '404 patents in *Latisse I* from the district court

through appeal. *Allergan, Inc. v. Apotex, Inc.*, No. 1:10-CV-681, 2013 WL 286251 (M.D.N.C. Jan. 24, 2013), *rev'd in part* 754 F.3d 952 (Fed. Cir. 2014).

154. Sandoz and Allergan, Inc. additionally completely litigated the issues of collateral estoppel of the '054, '988, '161 and '953 patents in *Latisse II* and *Latisse III* at the district court, and in the case of *Latisse III*, through appeal. *Allergan, Inc. v. Sandoz, Inc.*, No. 1:14-cv-1034 at Dkt. No. 71 (Order and Judgment); *Allergan, Inc. v. Sandoz, Inc.*, 2017 U.S. App. LEXIS 4733, at *17 (Fed. Cir. Mar. 17, 2017).

155. The prior judgments from *Latisse I*, *Latisse II*, and *Latisse III* are not appealable.

156. The prior judgments from *Latisse I*, *Latisse II*, and *Latisse III* are final and valid.

157. The Federal Circuit in *Latisse I* held that the asserted claims of the '029 patent were invalid as obvious. After the Federal Circuit's mandate issued, this Court entered a Final Judgment adjudging the asserted claims of the '029 patent invalid as obvious.

158. This Court issued entered Final Judgments regarding invalidity of the asserted claims in *Latisse II* and *Latisse III*.

159. Lastly, Allergan, Inc. and Duke had a full and fair opportunity to litigate invalidity in this Court and in the Federal Circuit in *Latisse I*.

160. Allergan, Inc. had a full and fair opportunity to litigate in this Court in *Latisse II*.

161. Allergan, Inc. and Duke had a full and fair opportunity to litigate in this Court and in the Federal Circuit in *Latisse III*.

162. *Latisse I*, *Latisse II*, and *Latisse III* were adversarial litigations.

163. There is no reason to doubt the quality, extensiveness, or fairness of procedures followed in *Latisse I*, *Latisse II*, and *Latisse III*.

164. For at least the foregoing reasons, Defendants are collaterally estopped from alleging infringement of Claims 22 and 30 of the '270 patent.

COUNT II

Actual Monopolization: Sham Litigation (*Latisse IV*) By Sandoz Against Allergan Sales, LLC and Duke (Violation of 15 U.S.C. § 2)

165. Sandoz repeats and realleges the allegations in paragraphs 1-164 as though fully set forth herein.

166. This claim arises under Section 2 of the Sherman Act, 15, U.S.C. § 2.

167. Jurisdiction is proper under 15 U.S.C. § 4 and 28 U.S.C. §§ 1331 and 1337.

Sham Litigation

168. Allergan, Inc. and/or Allergan Sales have sued Sandoz four times for patent infringement relating to the same product, Sandoz's bimatoprost ophthalmic solution, 0.03% product.

169. Duke has sued Sandoz three times for patent infringement relating to the same product, Sandoz's bimatoprost ophthalmic solution, 0.03% product.

170. Allergan Sales and Duke sued Sandoz in *Latisse IV*, not out of a genuine interest in redressing grievances, but for purposes of harassment. This lawsuit was brought as part of an anticompetitive scheme to prevent Sandoz and other potential competitors (for example, Apotex Inc.),² from launching their product, in order to prevent and delay competition. This lawsuit is not legitimate petitioning of the court.

² Upon information and belief, Apotex Inc. has received tentative approval from FDA to market and sell a substitute for LATISSE® on the US market. Upon information and belief, Apotex Inc. does not sell a substitute for LATISSE® on the US market.

171. In *Latisse I*, the Federal Circuit invalidated asserted claims of the '029 and '404 patents on the basis of obviousness.

172. Claims 22 and 30 of the '270 patent are substantially similar to, at least, Claims 1, 8, 14, 18, and 20 of the '029 patent and Claim 14 of the '404 patent, which were previously invalidated as obvious in *Latisse I*. Additionally, the '029 and '270 patents are related and share the same parent application.

173. In *Latisse II*, this Court held Allergan, Inc. collaterally estopped from asserting or contesting invalidity of the '988, '161, and '054 patents.

174. Claims 22 and 30 of the '270 patent are substantially similar to the claims of the '988, '161, and '054 patents that were previously invalidated on the basis of collateral estoppel in *Latisse II*.

175. This Court in *Latisse II* found that the claims of the '988, '161, and '054 patents recite substantially the same subject matter as invalid Claim 14 of the '404 patent.

176. In *Latisse III*, this Court held Allergan, Inc. collaterally estopped from asserting or contesting the invalidity of the asserted claims of the '953 patent.

177. Claims 22 and 30 of the '270 patent are substantially similar to Claims 8, 20, and 23 of the '953 patent, which were previously invalidated on the basis of collateral estoppel in *Latisse III*, a ruling affirmed by the Federal Circuit.

178. This Court in *Latisse III* found that the asserted claims of the '953 patent recite substantially the same subject matter as invalid Claim 14 of the '404 patent and invalid and the claims of the '988, '161, and '054 patents.

179. The '404, '054, '988, '161 and '953 patents are related and share the same parent application.

180. Allergan Sales is collaterally estopped from asserting Claims 22 and 30 of the '270 patent because they substantially similar to the patent claims previously litigated and held invalid in *Latisse I*, *Latisse II*, and *Latisse III*. The issue of obviousness in *Latisse I*, *Latisse II*, and *III* is identical to the issue of invalidity of the asserted claims of the '270 patent in the present case. Sandoz and Allergan, Inc. completely litigated the issue of obviousness of the asserted claims of the '029 and '404 patents in *Latisse I* from the district court through appeal (and had a full and fair opportunity to do so). *Allergan, Inc. v. Apotex, Inc.*, No. 1:10-CV-681, 2013 WL 286251 (M.D.N.C. Jan. 24, 2013), *rev'd in part* 754 F.3d 952 (Fed. Cir. 2014).

181. Sandoz and Allergan, Inc. additionally completely litigated the issues of collateral estoppel of the '054, '988, '161 and '953 patents in *Latisse II* and *Latisse III* in the district court, and in the case of *Latisse III* through appeal (and had a full and fair opportunity to do so). *Allergan, Inc. v. Sandoz, Inc.*, No. 1:14-cv-1034 at Dkt. No. 71 (Order and Judgment); *Allergan, Inc. v. Sandoz, Inc.*, 2017 U.S. App. LEXIS 4733, at *17 (Fed. Cir. Mar. 17, 2017).

182. The prior judgments from *Latisse I*, *Latisse II*, and *Latisse III* are final, valid, and not appealable.

183. At least by or around February 12, 2016, Sandoz warned Allergan, Inc. that asserting a patent Allergan, Inc. knew was not infringed would violate U.S. antitrust laws.

184. An invalid patent cannot be infringed.

185. On November 30, 2016, the application that ultimately issued as the '270 patent was allowed.

186. On December 8, 2016, Allergan sent Sandoz a letter stating that Allergan “understand[s] that Sandoz has launched at-risk a generic version of Allergan’s brand product LATISSE®.” Ex. 2, 12/8/2016 Ltr. from Allergan to Sandoz, at p. 1 (emphasis in original).

187. The letter from Allergan to Sandoz identifies the '953 patent as “covering LATISSE®” and that the parties had a “patent dispute” concerning the '953 patent. *Id.*

188. Despite the '270 patent application already having been allowed, the letter from Allergan to Sandoz does not identify the '270 patent as covering Sandoz's generic version of LATISSE®. *Id.* at 1-2.

189. In an apparent admission that the '270 patent is invalid and not infringed, the letter from Allergan to Sandoz does not identify the '270 patent as covering Sandoz's generic version of LATISSE®. *Id.* at 1-2.

190. On February 24, 2017, Allergan, Inc. represented in a 10K filing that “other products such as Estrace® Cream, . . . *Latisse*®, and Carafate® ***are not protected by patents*** in the United States where we sell these products.” Ex. 3, Allergan Inc. Form 10-K 2016, at p. 25 (emphasis added).

191. The '270 patent issued on February 28, 2017.

192. Upon information and belief, Allergan sent no letter to Sandoz, before or after, February 28, 2017 identifying the '270 patent as allegedly covering Sandoz's generic LATISSE®.

193. Upon information and belief, in or around March 2017, Allergan, Inc. listed the '270 patent in the Orange Book for LATISSE®.

194. Upon information and belief, Allergan sent no letter to Sandoz, before or after March 2017, identifying the '270 patent as allegedly covering Sandoz's generic LATISSE®.

195. Despite the foregoing, on July 7, 2017, Allergan Sales and Duke filed suit against Plaintiffs in *Latisse IV* alleging Sandoz's generic version of Allergan's LATISSE® infringed Claims 22 and 30 of the '270 patent, the same accused product in the prior *Latisse* litigations.

196. At least by July 7, 2017, Allergan Sales and Duke were aware that the '270 patent is related and claims priority to the '029 patent.

197. At least by July 7, 2017, Allergan Sales and Duke were aware that certain claims of the '029 patent had been found invalid.

198. At least by July 7, 2017, Allergan Sales and Duke were aware that Claims 22 and 30 of the '270 patent were substantially similar to the claims invalidated during the prior *Latisse* litigations, including Claim 1 of the '029 patent.

199. In light of the acts described above, Allergan Sales and Duke's legal filing in *Latisse IV* was not made not out of a genuine interest in redressing grievances.

200. Allergan Sales and Duke's complaining in *Latisse IV* was undertaken essentially for purposes of harassment.

201. Filings undertaken essentially for purposes of harassment are abuse of the judicial system.

202. *Latisse IV* is also objectively baseless because no reasonable litigant could realistically expect success on the merits. Rather, a reasonable litigant would expect Claims 22 and 30 of the '270 patent to be invalid as obvious in light of this Court's findings in *Latisse I*, *Latisse II*, and *Latisse III*, as detailed above.

203. A reasonable litigant would further expect to be collaterally estopped from contesting the invalidity of Claims 22 and 30 of the '270 patent on the basis that those claims are substantially the same as claims invalidated during *Latisse I*, *Latisse II*, and *Latisse III*, and because Allergan, Inc. had already been collaterally estopped from contesting the invalidity of substantially the same claims in *Latisse II* and *III*.

204. On February 24, 2017, Allergan, Inc. had also represented that there were no U.S. patents covering *Latisse*. Ex. 3, Allergan Inc. Form 10-K 2016, at p. 25.

205. In light of at least the foregoing, Allergan Sales and Duke could not reasonably expect to succeed on the allegations of infringement of Claims 22 and 30 of the '270 patent.

206. For at least the reasons set forth below, Allergan Sales and Duke also filed *Latisse IV* with the subjective motivation of interfering directly with the business relationships of Sandoz, a competitor.

207. On or around December 8, 2016, Allergan represented to Sandoz its concern that “[i]n just a short amount of time, the damage to Allergan as a result of Sandoz’s actions [i.e., launch of a generic version of Allergan’s brand product LATISSE®] could be tens of millions of dollars. Over time, the damage to Allergan could be in the hundreds of millions of dollars.” Ex. 2, 12/8/2016 Ltr. from Allergan to Sandoz, at p. 2.

208. Allergan was thus motivated to interfere with Sandoz’s sale of its bimatoprost ophthalmic solution, 0.03% product.

209. Duke was thus motivated to interfere with Sandoz’s sale of its bimatoprost ophthalmic solution, 0.03% product, based on its concern that launch of Sandoz’s bimatoprost ophthalmic solution, 0.03% product could allegedly result in a reduction of Duke’s royalties, which are proportional to Allergan’s profits.

Antitrust Injury

210. Allergan Sales and Duke’s sham litigation in *Latisse IV* is motivated by a desire to injure competition and Sandoz by pushing Sandoz and other potential competitors out of the relevant market, rather than pursue and obtain a justifiable legal remedy.

211. By pursuing the present sham litigation, Allergan Sales and Duke have caused antitrust injury to Sandoz including raising the cost of doing business directly or indirectly, and forestalling, frustrating and preventing Sandoz's ability to compete in the relevant market.

212. By filing *Latisse IV*, Allergan Sales and Duke have caused injury to Sandoz's business and property. Sandoz has diverted resources and has paid and continues to pay legal fees that would have not been required but for Allergan Sales and Duke's attempts to monopolize the market.

213. Allergan Sales and Duke's sham proceeding has also injured competition because Sandoz was forced to cease competition, negotiate a license or fight the frivolous lawsuit. Now Alcon has also been made to fight the frivolous lawsuit, incurring costs in connection with the sham litigation.

214. By pursuing the sham litigation in *Latisse IV*, Allergan Sales and Duke have also injured consumers. For example, upon information and belief, consumers have been deprived of the benefits of lower-priced generic competition for an FDA-approved treatment for hypotrichosis of the eyelashes as a result of the chilling effect from Defendants' sham litigation.

215. To the extent that Allergan Sales' profits have been reduced by Sandoz's entry into the market, as Allergan Sales purports, consumers benefitted from the competition by Sandoz through lower pricing. Allergan Sales and Duke's conduct directed at preventing or delaying Sandoz's and other competitor's entry into the market thus caused injury to competition in the market.

216. Upon information and belief, prior to when Sandoz launched its bimatoprost ophthalmic solution, 0.03% product, the prices for LATISSE® were at artificially high and monopolistic levels as a result of Allergan Sales and Duke's illicit and anticompetitive acts.

217. Upon information and belief, if Sandoz is enjoined from selling its bimatoprost ophthalmic solution, 0.03% product, the prices for LATISSE® will increase to artificially high and monopolistic levels as a result of Allergan Sales and Duke's illicit and anticompetitive acts.

218. Upon information and belief, Allergan Sales and Duke have not acted to advance their position by competing on the merits in the relevant market, but solely to exclude potential competition from an alternate source in the relevant market.

219. The effect of Allergan Sales and Duke's sham litigation will be to unreasonably restrain trade and commerce in the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT III

Actual Monopolization: Series of Sham Litigations By Sandoz Against Allergan and Duke (Violation of 15 U.S.C. § 2)

220. Sandoz repeats and realleges the allegations in paragraphs 1-219 as though fully set forth herein.

221. This claim arises under Section 2 of the Sherman Act, 15, U.S.C. § 2.

222. Jurisdiction is proper under 15 U.S.C. § 4 and 28 U.S.C. §§ 1331 and 1337.

Sham Litigations

223. Allergan and Duke have brought a whole series of legal proceedings against Sandoz.

224. Allergan has sued Sandoz four times for patent infringement relating to the same product, Sandoz's bimatoprost ophthalmic solution, 0.03% product.

225. Duke has sued Sandoz three times for patent infringement relating to the same product, Sandoz's bimatoprost ophthalmic solution, 0.03% product.

226. Allergan and Duke's whole series of legal filings were made, not out of a genuine interest in redressing grievances, but as part of a pattern or practice of successive filings undertaken for purposes of harassment. These lawsuits were brought as part of an anticompetitive scheme to prevent Sandoz and other potential competitors from launching their product, in order to prevent and delay competition. These lawsuits were not legitimate petitioning of the court.

227. In *Latisse I*, the Federal Circuit invalidated asserted Claims of the '029 and '404 patents on the basis of obviousness.

228. Claims 22 and 30 of the '270 patent are substantially similar to, at least, Claims 1, 8, 14, 18, and 20 of the '029 patent and Claim 14 of the '404 patent, which were previously invalidated as obvious in *Latisse I*. Additionally, the '029 and '270 patents are related and share the same specification, inventorship and parent application.

229. In *Latisse II*, this Court held Allergan, Inc. collaterally estopped from asserting or contesting invalidity of claims of the '988, '161, and '054 patents.

230. Claims 22 and 30 of the '270 patent are substantially similar to claims of the '988, '161, and '054 patents that were previously invalidated on the basis of collateral estoppel in *Latisse II*.

231. This Court in *Latisse II* found that Claims of the '988, '161, and '054 patents recite substantially the same subject matter as invalid Claim 14 of the '404 patent.

232. In *Latisse III*, this Court held Allergan, Inc. collaterally estopped from asserting or contesting the invalidity of the asserted claims of the '953 patent.

233. Claims 22 and 30 of the '270 patent are substantially similar to Claims 8, 20, and 23 of the '953 patent, which were previously invalidated on the basis of collateral estoppel in *Latisse III*.

234. This Court in *Latisse III* found that the asserted claims of the '953 patent recite substantially the same subject matter as invalid Claim 14 of the '404 patent and invalid and the claims of the '988, '161, and '054 patents. 14-cv-1034 at Dkt. No. 71.

235. The '404, '054, '988, '161 and '953 patents are related and share the same parent application.

236. Allergan Sales and Duke are collaterally estopped from asserting Claims 22 and 30 of the '270 patent because they cover substantially the same subject matter as patents previously litigated and held invalid in *Latisse I*, *Latisse II*, and *Latisse III*. The issue of obviousness in *Latisse I*, *Latisse II* and *III* are identical to the issues of invalidity of the asserted claims of the '270 patent in the present case. Sandoz and Allergan, Inc. completely litigated the issue of obviousness of the asserted claims of the '029 and '404 patents in *Latisse I* from the district court through appeal (and had a full and fair opportunity to do so). *Allergan, Inc. v. Apotex, Inc.*, No. 1:10-CV-681, 2013 WL 286251 (M.D.N.C. Jan. 24, 2013), *rev'd in part* 754 F.3d 952 (Fed. Cir. 2014).

237. Sandoz and Allergan, Inc. additionally completely litigated the issues of collateral estoppel of the '054, '988, '161 and '953 patents in *Latisse II* and *Latisse III* in the district court, and in the case of *Latisse III*, through appeal (and had a full and fair opportunity to do so). *Allergan, Inc. v. Sandoz, Inc.*, No. 1:14-cv-1034 at Dkt. No. 71 (Order and Judgment); *Allergan, Inc. v. Sandoz, Inc.*, 2017 U.S. App. LEXIS 4733, at *17 (Fed. Cir. Mar. 17, 2017).

238. The prior judgments from *Latisse I*, *Latisse II*, and *Latisse III* are final, valid, and not appealable.

239. At least by or around February 12, 2016, Sandoz warned Allergan, Inc. that asserting a patent Allergan, Inc. knew was not infringed would violate U.S. antitrust laws.

240. An invalid patent cannot be infringed.

241. On November 30, 2016, the application that ultimately issued as the '270 patent was allowed.

242. On December 8, 2016, Allergan sent Sandoz a letter stating that Allergan “understand[s] that Sandoz has **launched at-risk** a generic version of Allergan’s brand product LATISSE®.” Ex. 2, 12/8/2016 Ltr. from Allergan to Sandoz, at p. 1 (emphasis in original).

243. The letter from Allergan to Sandoz identifies the '953 patent as “covering LATISSE®” and that the parties had a “patent dispute” concerning the '953 patent. *Id.*

244. Despite the '270 patent application already having been allowed, the letter from Allergan to Sandoz does not identify the '270 patent as covering Sandoz’s generic version of LATISSE®. *Id.* at 1-2.

245. In an apparent admission that the '270 patent is invalid and not infringed, the letter from Allergan to Sandoz does not identify the '270 patent as covering Sandoz’s generic version of LATISSE®. *Id.* at 1-2.

246. On February 24, 2017, Allergan, Inc. represented in a 10K filing that “other products such as Estrace® Cream, . . . *Latisse*®, and Carafate® ***are not protected by patents*** in the United States where we sell these products.” Ex. 3, Allergan Inc. Form 10-K 2016, at p. 25 (emphasis added).

247. The '270 patent issued on February 28, 2017.

248. Upon information and belief, Allergan sent no letter to Sandoz, before or after February 28, 2017, identifying the '270 patent as allegedly covering Sandoz's generic LATISSE®.

249. Upon information and belief, in or around March, 2017, Allergan, Inc. listed the '270 patent in the Orange Book for LATISSE®.

250. Upon information and belief, Allergan, Inc. sent no letter to Sandoz, before or after March 2017, identifying the '270 patent as allegedly covering Sandoz's generic LATISSE®.

251. Despite the foregoing, on July 7, 2017, Allergan Sales and Duke filed suit against Plaintiffs alleging Sandoz's generic version of Allergan Sales' LATISSE® infringed Claims 22 and 30 of the '270 patent.

252. At least by July 7, 2017, Allergan and Duke were aware that the '270 patent is related and claims priority to the '029 patent.

253. At least by July 7, 2017, Allergan and Duke were aware that certain claims of the '029 patent had been found invalid.

254. At least by July 7, 2017, Allergan and Duke were aware that Claims 22 and 30 of the '270 patent were substantially similar to the claims invalidated during the prior *Latisse* litigations, including Claim 1 of the '029 patent.

255. In light of the acts described above, Allergan and Duke's legal filings were made not out of a genuine interest in redressing grievances.

256. Allergan and Duke's repetitive litigations against Sandoz evidence a pattern, practice and policy of successive filings undertaken essentially for purposes of harassment.

257. Successive filings undertaken essentially for purposes of harassment is abuse of the judicial system.

258. On February 24, 2017, Allergan, Inc. had also represented that there were no U.S. patents covering LATISSE®. Ex. 3, Allergan Inc. Form 10-K 2016, at p. 25.

259. On or around December 8, 2016, Allergan represented to Sandoz its concern that “[i]n just a short amount of time, the damage to Allergan as a result of Sandoz’s actions [i.e., launch of a generic version of Allergan’s brand product LATISSE®] could be tens of millions of dollars. Over time, the damage to Allergan could be in the hundreds of millions of dollars.” Ex. 2, 12/8/2016 Ltr. from Allergan to Sandoz, at p. 2.

260. Allergan was thus motivated to interfere with Sandoz’s sale of its bimatoprost ophthalmic solution, 0.03% product.

261. Duke was thus motivated to interfere with Sandoz’s sale of its bimatoprost ophthalmic solution, 0.03% product, based on its concern that launch of Sandoz’s bimatoprost ophthalmic solution, 0.03% product could allegedly result in a reduction of Duke’s royalties, which are proportional to Allergan’s profits.

Antitrust Injury

262. Allergan and Duke’s sham litigations were motivated by a desire to injure competition and Sandoz by pushing Sandoz and other potential competitors out of the relevant market, rather than pursue and obtain a justifiable legal remedy.

263. By bringing and maintaining these sham litigations, Allergan and Duke have caused antitrust injury to Sandoz including raising the cost of doing business directly or indirectly, and forestalling, frustrating and preventing Sandoz’s ability to compete in the relevant market.

264. By bringing and maintaining four lawsuits concerning LATISSE® and the same accused product, Allergan and Duke have caused injury to Sandoz’s business and property.

Sandoz and Alcon have diverted resources to the litigations and have paid and continue to pay legal fees that would have not have been required but for Allergan's attempts to monopolize the market.

265. Allergan and Duke's series of sham proceedings have also injured competition because Sandoz was forced to cease competition, negotiate a license or fight the frivolous lawsuits. Now Alcon has also been made to fight the frivolous lawsuits, incurring costs in connection with the sham litigations. Had Allergan and Duke been successful in the sham litigation proceedings, Sandoz would have been forced out of the market, and higher prices would have resulted, causing injury to consumers and competition. Because Sandoz chose to oppose the series of sham litigations, rather than voluntarily exit the market, Sandoz has incurred attorneys' fees and other costs in connection with its competition.

266. By pursuing these sham litigations, Allergan and Duke have also injured consumers. For example, upon information and belief, consumers have been deprived of the benefits of lower-priced generic competition for an FDA-approved treatment for hypotrichosis of the eyelashes as a result of the chilling effect from Defendants' sham litigations.

267. To the extent that Allergan Sales' profits have been reduced by Sandoz's entry into the market, as Allergan Sales purports, consumers benefitted from the competition by Sandoz through lower pricing. Allergan and Duke's conduct directed at preventing or delaying Sandoz's and other competitor's entry into the market thus caused injury to competition in the market.

268. Upon information and belief, prior to when Sandoz launched its bimatoprost ophthalmic solution, 0.03% product, the prices for LATISSE® were at artificially high and monopolistic levels as a result of Allergan and Duke's illicit and anticompetitive acts.

269. Upon information and belief, if Sandoz is enjoined from selling its bimatoprost ophthalmic solution, 0.03% product, the prices for LATISSE® will increase to artificially high and monopolistic levels as a result of Defendants' illicit and anticompetitive acts.

270. Upon information and belief, Defendants have not acted to advance their position by competing on the merits in the relevant market, but solely to exclude potential competition from an alternate source in the relevant market.

271. The effect of Allergan and Duke's sham litigations will be to unreasonably restrain trade and commerce in the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT IV

Attempted Monopolization in Violation of the Sherman Act By Sandoz Against Allergan and Duke (Violation of 15 U.S.C. § 2)

272. Sandoz repeats and realleges the allegations in paragraphs 1-271 as though fully set forth herein.

273. On December 8, 2016, Allergan sent Sandoz a letter stating that Allergan "understand[s] that Sandoz has launched at-risk a generic version of Allergan's brand product LATISSE®." Ex. 2, 12/8/2016 Ltr. from Allergan to Sandoz, at p. 1.

274. The letter from Allergan to Sandoz identifies the '953 patent as "covering LATISSE®" and that the parties had a "patent dispute" concerning the '953 patent. *Id.*

275. The '270 patent issued on February 28, 2017.

276. Upon information and belief, Allergan sent no letter to Sandoz, before or after February 28, 2017, identifying the '270 patent as allegedly covering Sandoz's generic LATISSE®.

277. Upon information and belief, in or around March 2017, Allergan, Inc. listed the '270 patent in the Orange Book for LATISSE®.

278. Upon information and belief, Allergan, Inc. sent no letter to Sandoz, before or after March 2017, identifying the '270 patent as allegedly covering Sandoz's generic LATISSE®.

279. Allergan represented to Sandoz in its December 2016 letter that "[i]n just a short amount of time, the damage to Allergan as a result of Sandoz's actions could be tens of millions of dollars. Over time, the damage to Allergan could be in the hundreds of millions of dollars." Ex. 2, 12/8/2016 Ltr. from Allergan to Sandoz, at p. 2.

280. Allergan was thus motivated to interfere with Sandoz's sale of its bimatoprost ophthalmic solution, 0.03% product.

281. Duke was thus motivated to interfere with Sandoz's sale of its bimatoprost ophthalmic solution, 0.03% product, based on its concern that launch of Sandoz's bimatoprost ophthalmic solution, 0.03% product could allegedly result in a reduction of Duke's royalties, which are proportional to Allergan's profits.

282. Allergan and Duke's actions evidence their specific intent to restrain and destroy competition in the relevant market.

283. As detailed above, despite knowing that Allergan and Duke were estopped from asserting or contesting the invalidity of the claims of the '270 patent and that those patent claims were invalid as obvious, Allergan and Duke brought an objectively baseless lawsuit asserting the '270 patent against Plaintiffs pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring Sandoz, a market rival, and eliminating all the competition in the market.

284. Despite knowing that Allergan and Duke were estopped from asserting or contesting the invalidity of the claims of the '270 patent and that those patent claims were invalid as obvious, Allergan and Duke brought a series of lawsuits against Plaintiffs pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring Sandoz, a market rival.

285. Allergan and Duke thus have brought their patent infringement claims in bad faith, for an improper purpose, and as a means of directly interfering with and harming Sandoz's business and in order to destroy competition by Sandoz.

286. Defendants have engaged in an overall predatory scheme to monopolize the relevant market through, but not limited to, initiating sham judicial proceedings designed to restrain competition and effectuate a monopoly for a bimatoprost ophthalmic solution, 0.03% product.

287. Allergan and Duke's anticompetitive and monopolistic actions evince its overall predatory scheme to injure or destroy competition in the relevant market. Allergan Sales and Duke have improperly wielded the '270 patent as an anticompetitive weapon in order to consolidate, entrench and enhance their monopolistic position in the relevant market and to stifle and eliminate competition and competitors with no economic, market or competitive benefit.

288. Allergan and Duke intentionally engaged in the exclusionary conduct alleged herein with the express purpose of achieving and maintaining monopoly power in the market for bimatoprost ophthalmic solution, 0.03% products.

289. This is evidenced, *inter alia*, by Allergan representing to Sandoz that Allergan would suffer "hundreds of millions of dollars" in damage for Allergan's loss of monopoly

power, which would also result in a reduction of Duke's royalties, which are proportional to Allergan's profits. Ex. 2, 12/8/2016 Ltr. from Allergan to Sandoz, at p. 2.

290. Allergan Sales and Duke are seeking to enjoin Plaintiffs from making, selling, and offering to sell a bimatoprost ophthalmic solution, 0.03% product.

291. By seeking to enjoin Plaintiffs from making, selling, and offering to sell a bimatoprost ophthalmic solution, 0.03% product, coupled with other market structure and conduct evidence, including, but not limited to, the lack of other competition for a bimatoprost ophthalmic solution, 0.03% product, Allergan and Duke have created a dangerous probability that they will achieve their goal of monopolizing the relevant market.

292. Allergan and Duke's market share in the relevant market, coupled with other market structure and conduct evidence, including, but not limited to, the lack of other competition for a bimatoprost ophthalmic solution, 0.03% product, the likely effect of competitive entry, the nature of the anticompetitive conduct alleged herein, and related economic and market factors, constitutes a dangerous probability that Allergan and Duke will succeed in their efforts to maintain a monopoly in the relevant market.

293. Allergan and Duke's sham litigations were motivated by a desire to injure competition and Sandoz by pushing Sandoz out of the bimatoprost ophthalmic solution, 0.03% product market, rather than pursue and obtain a justifiable legal remedy.

294. By pursuing the sham litigations, Allergan and Duke have caused antitrust injury including, *inter alia*: (1) injury to Sandoz including raising the cost of doing business directly or indirectly, and forestalling, frustrating and preventing Sandoz's ability to compete in the relevant market; (2) upon information and belief, injury to third-party competitors, by frustrating, discouraging, and forestalling third-party competitors from entering the relevant market; and (3)

upon information and belief, injury to consumers, including depriving consumers of the benefits of lower-priced generic competition for an FDA-approved treatment for hypotrichosis of the eyelashes as a result of the chilling effect from Defendants' sham litigation.

295. Upon information and belief, Allergan and Duke have not acted to advance their position by competing on the merits in the relevant market, but solely to exclude potential competition from an alternate source in the relevant market.

296. There is a dangerous probability that Allergan and Duke will succeed in monopolizing the relevant market through the predatory conduct alleged above.

297. The effect of Allergan and Duke's overall scheme, course of conduct and attempt to monopolize will be to unreasonably restrain trade and commerce in the relevant market, and permit Defendants to monopolize the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT V

Conspiracy to Monopolize By Sandoz Against Allergan and Duke (Violation of 15 U.S.C. §§ 1 and 2)

298. Sandoz repeats and realleges the allegations in paragraphs 1-297 as though fully set forth herein.

299. Upon information and belief, on or around December 18, 2007, Duke, Allergan, Inc., and Allergan Sales, LLC entered into a license agreement whereby Duke exclusively licensed certain Duke patents, including the '270 patent asserted in this case as well as the '029 patent asserted in *Latisse I* and the '962 patent asserted in *Latisse III*, to Allergan. Ex. 4 [License Agreement] at Appendix A.

300. Under the terms of the agreement, Allergan was required to pay Duke a non-refundable, non-creditable running royalty of 2% on net sales of LATISSE®. Ex. 4 [License Agreement], Section 3.03.

301. Thus, the amount of royalties Duke was to receive from Allergan relating to the sale of LATISSE® was directly proportional to the net sales of LATISSE®.

302. The 2007 license agreement also included a section entitled “INFRINGEMENT OF DUKE’S PATENT RIGHTS BY THIRD PARTIES,” which specified that Allergan had the right to “prosecute at its own expense any [alleged] infringement” of the licensed patents, including the ’270, ’029 and ’962 patents. Ex. 4 [License Agreement], Section 8.02(b).

303. Irrespective of the merits of the case, if Duke was a necessary party to such infringement lawsuit, then Duke would “agree[] to join the lawsuit as a party plaintiff.” Ex. 4 [License Agreement], Section 8.02(b).

304. According to the terms of the agreement, if Allergan did not bring a patent infringement lawsuit within a specified time, “Duke shall have the right ... to prosecute at its own expense any such [alleged] infringements” of the licensed patents, including the ’270, ’029, and ’962 patents. Ex. 4 [License Agreement], Section 8.03.

305. Irrespective of the merits of Duke’s case, the parties further agreed that “Duke may use the name of [Allergan] as a party plaintiff.” Ex. 4 [License Agreement], Section 8.03.

306. Knowing that Defendants would be estopped from asserting or contesting the invalidity of the claims of the ’270 and ’962 patents, Defendants chose to enter into an explicit and implicit conspiracy under which Defendants agreed to enforce licensed patents, including the ’270 and ’962 patents, against any generic competitor in order to prohibit entry of such generic

competitor by obtaining an undeserved 30-month stay against FDA approval of such generic competitor's Abbreviated New Drug Application ("ANDA").

307. Duke and Allergan Sales have asserted the '270 patent against Plaintiffs in *Latisse IV* as part of this conspiracy.

308. Duke and Allergan, Inc. asserted the '962 patent against Sandoz in *Latisse III* as part of this conspiracy.

309. Duke and Allergan have continued to prosecute patents related to the '270, '029 and '962 as part of this conspiracy.

310. The terms of Duke and Allergan's license agreement relating to enforcement of patents against third parties affects interstate commerce by effectively preventing any third party ANDA filer from selling generic LATISSE® for 30 months from its ANDA filing date provided Defendants bring suit within 45 days of receiving the third-party's notice letter.

311. Upon information and belief, Duke and Allergan entered into such conspiracy in order to fix prices for LATISSE® at a high level while restraining trade or commerce in the generic LATISSE® market by suppressing competition.

312. Upon information and belief, the conspiracy between Duke and Allergan was entered into with the specific intent to maintain Duke and Allergan's monopoly power in the relevant market and to attempt to monopolize the relevant market.

313. Upon information and belief, Duke and Allergan had a meeting of the minds in respect of such unlawful arrangement, and a unity of purpose, design and understanding to engage in such unlawful conspiracy.

314. Duke and Allergan's conspiracy was motivated by a desire to injure competition and Sandoz by pushing Sandoz out of the bimatoprost ophthalmic solution, 0.03% product market, rather than pursue and obtain a justifiable legal remedy.

315. Duke and Allergan's conspiracy has caused antitrust injury including, *inter alia*: (1) injury to Sandoz including raising the cost of doing business directly or indirectly, and forestalling, frustrating and preventing Sandoz's ability to compete in the relevant market; (2) upon information and belief, injury to third-party competitors, by frustrating, discouraging, and forestalling third-party competitors from entering the relevant market; and (3) upon information and belief, injury to consumers by depriving consumers of the benefits of lower-priced generic competition for an FDA-approved treatment for hypotrichosis of the eyelashes as a result of the chilling effect from Defendants' conspiracy.

316. Duke and Allergan's actions are intended to protect their market power in the relevant market and comprise an unlawful contract and conspiracy in restraint of trade in violation of §§ 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2.

COUNT VI

Declaration of Unenforceability Due To Patent Misuse By Sandoz and Alcon Against Allergan Sales and Duke

317. Plaintiffs repeat and reallege the allegations in paragraphs 1-316 as though fully set forth herein.

318. Upon information and belief, the '270 patent is unenforceable against Plaintiffs as a result of Defendants' patent misuse.

319. Duke and Allergan Sales have committed patent misuse rendering the '270 patent unenforceable as a matter of law by enforcing and asserting the '270 patent against Plaintiffs even though no reasonable litigant could believe that the '270 patent was valid.

320. First, Duke and Allergan Sales' allegations of infringement of the '270 patent were made in bad faith.

321. As detailed *supra*, a reasonable litigant would expect Claims 22 and 30 of the '270 patent to be invalid as obvious in light of this Court's invalidity holdings in *Latisse I*, *Latisse II*, and *Latisse III*.

322. As detailed *supra*, a reasonable litigant would further expect to be collaterally estopped from asserting or contesting the invalidity of Claims 22 and 30 of the '270 patent on the basis that those claims are substantially similar to the claims held to be invalid during *Latisse I*, *Latisse II*, and *Latisse III*, and because Allergan, Inc. had already been collaterally estopped from asserting or contesting the invalidity of substantially similar claims in *Latisse II* and *III*.

323. Allergan had also already admitted by at least February 24, 2017 that there were no U.S. patents covering LATISSE®, despite having received a notice of allowance for the '270 patent. Ex. 3, Allergan Inc. Form 10-K 2016, at p. 25.

324. Accordingly, no reasonable litigant could realistically expect success on the merits with respect to Defendants' allegations of infringement of Claims 22 and 30 of the '270 patent.

325. Second, Allergan Sales and Duke had an improper purpose in asserting the '270 patent against Plaintiffs. As detailed *supra*, Allergan Sales and Duke's goal in suing Plaintiffs for alleged infringement of the '270 patent was not to win a favorable judgment, but to harass Plaintiffs and deter others from competition by engaging the litigation process itself, regardless of the outcome.

326. On December 8, 2016, Allergan sent Sandoz a letter stating that Allergan “understand[s] that Sandoz has launched at-risk a generic version of Allergan’s brand product LATISSE®.” Ex. 2, 12/8/2016 Ltr. from Allergan to Sandoz, at p. 1.

327. Allergan’s letter did not mention the ’270 patent, despite the fact that the ’270 patent application had already been allowed.

328. Allergan represented to Sandoz in its letter that “[i]n just a short amount of time, the damage to Allergan as a result of Sandoz’s actions could be tens of millions of dollars. Over time, the damage to Allergan could be in the hundreds of millions of dollars.” *Id.* at 2.

329. Allergan was thus motivated to interfere with Sandoz’s sale of its bimatoprost ophthalmic solution, 0.03% product, based on its concern that launch of Sandoz’s bimatoprost ophthalmic solution, 0.03% product could allegedly result in “hundreds of millions of dollars” in “damage” to Allergan, and a reduction of Duke’s royalties, which are proportional to Allergan’s profits.

330. Duke was thus motivated to interfere with Sandoz’s sale of its bimatoprost ophthalmic solution, 0.03% product, based on its concern that launch of Sandoz’s bimatoprost ophthalmic solution, 0.03% product could allegedly result in a reduction of Duke’s royalties, which are proportional to Allergan’s profits.

331. The ’270 patent issued on February 28, 2017.

332. Upon information and belief, Allergan sent no letter to Sandoz, before or after February 28, 2017, identifying the ’270 patent as allegedly covering Sandoz’s generic LATISSE®.

333. Upon information and belief, in or around March 2017, Allergan, Inc. listed the ’270 patent in the Orange Book for LATISSE®.

334. Upon information and belief, Allergan, Inc. sent no letter to Sandoz, before or after March 2017, identifying the '270 patent as allegedly covering Sandoz's generic LATISSE®.

335. Third, Duke and Allergan Sales' enforcement of the '270 patent impermissibly broadens the scope of the '270 patent. As detailed *supra*, no reasonable litigant would believe that Claims 22 and 30 of the '270 patent are valid. A reasonable litigant would further believe that Duke and Allergan Sales are collaterally estopped from asserting or contesting the invalidity of Claims 22 and 30 of the '270 patent.

336. By asserting Claims 22 and 30 of the '270 patent against Plaintiffs, Duke and Allergan Sales are at least physically broadening the scope of the '270 patent by attempting to exclude a product not covered by a valid patent.

337. By asserting Claims 22 and 30 of the '270 patent against Plaintiffs, Duke and Allergan Sales are at least temporally broadening the scope of the '270 patent by attempting to exclude a product not covered by a valid patent

338. Fourth, the manner in which Duke and Allergan Sales have broadened the scope of the '270 patent has an anticompetitive effect.

339. On information and belief, Allergan Sales has market power in the relevant market.

340. Upon information and belief, LATISSE® has resulted in net sales for Allergan Sales of over \$70 million annually since its launch in 2009.

341. Upon information and belief, if Duke and Allergan Sales are successful in enjoining Plaintiffs from competing in the relevant market, Allergan Sales would have a monopoly share of the relevant market.

342. As detailed *supra*, Duke and Allergan Sales enforcement of the '270 patent against Plaintiffs has anticompetitive effects including: (1) raising the cost for Plaintiffs of doing business directly or indirectly, and forestalling, frustrating and preventing Plaintiffs' ability to compete in the relevant market; (2) upon information and belief, injury to third-party competitors by frustrating, discouraging, and forestalling third-party competitors from entering the relevant market; and (3) upon information and belief, depriving consumers of the benefits of lower-priced generic competition for an FDA-approved treatment for hypotrichosis of the eyelashes, as a result of the chilling effect from Defendants' sham litigations.

343. As detailed *supra*, Duke and Allergan Sales' attempt to monopolize the relevant market is additionally in violation of Section 2 of the Sherman Act. This further evidences Duke and Allergan Sales bad faith and improper purpose in enforcing the '270 patent against Plaintiffs. Duke and Allergan Sales' antitrust violations demonstrate the anticompetitive effect from Duke and Allergan Sales' allegations of infringement of the '270 patent.

344. Because Allergan Sales has market power in the relevant market and Duke and Allergan Sales are asserting claims of the '270 patent that no reasonable litigant would believe to be valid, Duke and Allergan Sales have misused the '270 patent, rendering it unenforceable against Plaintiffs.

COUNT VII

Declaration of Unenforceability Due To Equitable Estoppel By Sandoz Against Allergan Sales and Duke

345. Sandoz repeats and realleges the allegations in paragraphs 1-345 as though fully set forth herein.

346. The '270 patent is unenforceable against Sandoz due to estoppel, including without limitation the doctrine of equitable estoppel.

347. On November 30, 2016, the '270 patent application was allowed.

348. On or around December 5, 2016, Sandoz launched a generic version of Latisse®.

349. On or around December 8, 2016, Allergan sent Sandoz a letter stating that Allergan “understand[s] that Sandoz has **launched at-risk** a generic version of Allergan’s brand product LATISSE®.” Ex. 2, 12/8/2016 Ltr. from Allergan to Sandoz, at p. 1.

350. The letter from Allergan to Sandoz identifies the '953 patent as “covering LATISSE®” and that the parties had a “patent dispute” concerning the '953 patent. *Id.*

351. Despite the '270 patent having already been allowed by December 8, 2016, Allergan did not identify the '270 patent in its letter as potentially covering Sandoz’s generic LATISSE®.

352. Despite the '270 patent having already been allowed by December 8, 2016, Allergan did not identify the '270 patent as covering LATISSE® in its 2016 year-end 10K filing. Ex. 3, Allergan Inc. Form 10-K 2016, at p. 25.

353. The '270 patent issued on February 28, 2017.

354. The Federal Circuit invalidated the asserted claims of the '953 patent on March 17, 2017. *Allergan, Inc. v. Sandoz, Inc.*, 681 Fed.Appx. 955 (Fed. Cir. 2017).

355. Upon information and belief, Allergan sent no letter to Sandoz, before or after February 28, 2017, identifying the '270 patent as allegedly covering Sandoz’s generic LATISSE®.

356. Allergan’s letter to Sandoz indicated that it did not intend to press an infringement claim against Sandoz relating to the '270 patent.

357. Allergan’s letter identifies the '953 patent as the only patent putting Sandoz “at-risk” for further action by Allergan.

358. Allergan's letter does not mention the '270 patent application, even though Allergan knew, upon information and belief, that it would have potential rights to enforce the '270 patent after the '270 patent issued.

359. The statements in Allergan's letter thus support an inference that Allergan did not intend to allege infringement of the '270 patent against Plaintiffs.

360. Sandoz substantially relied on Allergan's misleading communications set forth in its letter.

361. Due to Sandoz's reliance on Allergan's misleading communications set forth in its letter, Sandoz will be materially prejudiced if Defendants are permitted to proceed with asserting the '270 patent against Sandoz. In reliance on Allergan's misleading communications, Sandoz did not change course, and continued to invest significant time and money developing their products and offering them to market without any perceived need to alter them due to alleged infringement of the '270 patent.

362. Sandoz is therefore entitled to a declaration that Defendants are equitably estopped from bringing a claim of infringement of the '270 patent against Sandoz.

COUNT VIII

Declaration of Non-Infringement of the '270 Patent By Alcon Against Allergan Sales and Duke

363. Alcon repeats and realleges the allegations in paragraphs 1-362 as though fully set forth herein.

364. Alcon has not and does not market a generic version of LATISSE®.

365. Alcon has not and does not sell a generic version of LATISSE®.

366. Alcon has not and does not promote a generic version of LATISSE®.

367. Alcon has not and does not distribute a generic version of LATISSE®.

368. Alcon manufactures bimatoprost ophthalmic solution, 0.03%.

369. Alcon does not provide its bimatoprost ophthalmic solution, 0.03% to patients.

370. Alcon does not provide its bimatoprost ophthalmic solution, 0.03% to healthcare providers.

371. Alcon does not include a prescription drug label with its bimatoprost ophthalmic solution, 0.03%.

372. Prior to when Allergan Sales and Duke filed suit against Alcon in *Latisse IV*, Alcon lacked knowledge of the '270 patent.

373. Alcon thus lacked knowledge that the purported induced acts allegedly constituted infringement of the '270 patent.

374. Alcon has not induced infringement of the '270 patent.

375. Alcon has not contributed to the infringement of the '270 patent.

376. As a result of the acts described in the foregoing paragraphs, there exists a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of non-infringement of Claims 22 and 30 of the '270 patent by Alcon.

377. A judicial declaration is necessary and appropriate so that Alcon may ascertain its rights regarding the '270 patent.

COUNT IX

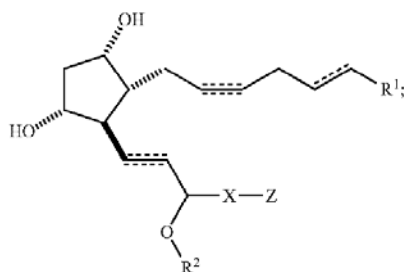
Declaration of Invalidity of the '270 Patent By Sandoz and Alcon Against Allergan Sales and Duke

378. Plaintiffs repeat and reallege the allegations in paragraphs 1-377 as though fully set forth herein.

379. The '270 patent is invalid for failure to meet the conditions of patentability and/or otherwise comply with one or more of 35 U.S.C. §§ 100 *et seq.*, 101, 102, 103, and 112. By way of example, Claims 22 and 30 of the '270 patent lack written description support as required by Section 112. Claims 22 and 30 describe a subgenus of compositions, each reciting that R¹ is C(O)NHR³.

380. Claim 22 is representative. Claim 22 depends from claim 17. Claim 17 recites:

17. A method of growing hair, wherein the method comprises topically applying to mammalian skin a safe and effective amount of a composition comprising: A) An active ingredient selected from the group consisting of a prostaglandin F analog of the following structure:



and pharmaceutically acceptable salts thereof;

wherein R¹ is selected from the group consisting of C(O)NHOH, C(O)NHR³, and C(O)NHS(O)₂R⁴;

R² is a hydrogen atom;

R³ is methyl, ethyl or isopropyl;

R⁴ is phenyl or methyl;

X is selected from the group consisting of --C≡C--, a covalent bond, --CH=C=CH--, --CH=CH--, --CH=N--, --C(O)--, --C(O)Y--, and --(CH₂)_n--, wherein n is 2 to 4;

Y is selected from the group consisting of a sulfur atom, an oxygen atom, and NH; and

Z is selected from the group consisting of a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a

substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group.

381. Claim 22 recites “[t]he method of claim 17, wherein R^1 is $C(O)NHR^3$.”

382. There are no examples in the specification of compositions comprising R^1 that is $C(O)NHR^3$, as required by both Claims 22 and 30. There are no blaze marks in the specification for a preference of R^1 being $C(O)NHR^3$. Accordingly, there is no evidence that the inventors of the ’270 patent possessed the claimed subgenera at the time of their alleged invention.

383. Claims 22 and 30 of the ’270 patent are also obvious in light International Patent Application No. PCT/US98/02889 (“Johnstone”) in combination with U.S. Patent No. 5,688,819 (the “’819 patent”).

384. Johnstone is prior art to the ’270 patent.

385. The ’819 patent is prior art to the ’270 patent.

386. Claims 22 and 30 of the ’270 patent describe methods of using prostaglandin F analogs to grow hair.

387. A person of ordinary skill in the art at the time of the alleged ’270 patent invention would have been motivated to combine the teachings of Johnstone with the teachings of the ’819 patent.

388. Johnstone discloses that prostaglandin F analogs used to treat glaucoma can also be used to grow hair.

389. Johnstone also discloses specific classes of compositions of prostaglandin F analogs.

390. The ’819 patent discloses a set of selective prostaglandin F analogs, including bimatoprost, which is specifically identified by its chemical structure.

391. The classes of prostaglandin F analogs disclosed by Johnstone would guide a person of ordinary skill in the art to compounds with similar structures that would fall within the scope of Claims 22 and 30 of the '270 patent, such as those disclosed by the '819 patent.

392. A person of ordinary skill in the art reading Johnstone would also have had a reasonable expectation of success at achieving the alleged invention described in Claims 22 and 30 of the '270 patent.

393. Johnstone's teaching provides specific guidance as to what parameters would lead to success of using specific prostaglandin F analogs to grow hair.

394. Johnstone's teaching thus provides specific guidance as to what parameters would lead to a reasonable expectation of success of achieving the alleged invention described in Claims 22 and 30 of the '270 patent.

395. Any purported secondary considerations of non-obviousness are not claimed, are not novel, and are not commensurate in scope with the alleged invention described in Claims 22 and 30 of the '270 patent.

396. As a result of the acts described in the foregoing paragraphs, there exists a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of Claims 22 and 30 of the '270 patent.

397. A judicial declaration is necessary and appropriate so that Alcon may ascertain its rights regarding the '270 patent.

COUNT X

Declaration of Non-Infringement of the '270 Patent By Sandoz Against Allergan Sales and Duke

398. Based on the foregoing Paragraphs, which are hereby incorporated by reference, asserted claims 22 and 30 of the '270 patent are invalid. Invalid patent claims cannot be infringed.

399. As a result of the acts described in the foregoing paragraphs, there exists a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of non-infringement of Claims 22 and 30 of the '270 patent by Sandoz.

400. A judicial declaration is necessary and appropriate so that Sandoz may ascertain its rights regarding the '270 patent.

EXCEPTIONAL CASE

401. This case is an exceptional one, and Sandoz and Alcon are entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Sandoz and Alcon respectfully request that judgment be entered in their favor and pray the Court grant the following relief to Plaintiffs:

- A. An entry of judgment in favor of Plaintiffs and against Defendants;
- B. An entry of judgment declaring that Plaintiffs have not infringed, either directly or indirectly, Claims 22 and 30 of the '270 patent;
- C. An entry of judgment declaring that Claims 22 and 30 of the '270 patent are invalid and unenforceable;

D. An entry of judgment declaring that Defendants are collaterally estopped from asserting Claims 22 and 30 of the '270 patent against Plaintiffs or contesting their invalidity;

E. An entry of judgment declaring that Defendants are equitably estopped from asserting claims 22 and 30 of the '270 patent against Sandoz;

F. An entry of judgment declaring that the '270 patent is unenforceable against Plaintiffs on the basis of patent misuse;

G. Treble damages attributable to Defendants' unlawful attempted monopolization pursuant to Section 2 of the Sherman Act, 15 U.S.C. § 2;

H. An order declaring that Plaintiffs are the prevailing party and that this is an exceptional case, awarding Plaintiffs costs, expenses, disbursements, and reasonable attorney fees under 35 U.S.C. § 285 and all other applicable statutes, rules, and common law; and

I. Such other and further relief as this Court may deem just and proper.

REQUEST FOR JURY TRIAL

In accordance with Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs respectfully request a jury trial on all issues triable to a jury in this action.

Dated: September 14, 2017

Respectfully Submitted,

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